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Research Article

Levobupivacaine versus Bupivacaine in Ultrasound Guided Suprazygomatic Maxillary Nerve Block in Maxillofacial Surgery

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Abstract

Background: Maxillary nerve block provides optimal postoperative pain management after maxillary osteotomy in adults.

Objective: To compare the efficacy of Levobupivacaine versus Bupivacaine on the postoperative pain through ultrasound guided Suprazygomatic maxillary nerve block in adult maxillofacial surgery.

Methods: Patients were allocated into three groups (35 patients in each group): maxillary nerve block with Levobupivacaine group (group-L), maxillary nerve block with a Bupivacaine group (group-B) and fentanyl group (group-F) at Mansoura University Hospital. Statistical analysis was carried out using the Statistical Package for Social Sciences (SPS)

Results: The study was completed on 105 patients and most of our patients in all groups were females (84.8%) and ASA I (86.7%). Heart rate changes and MAP in Group B and group L was significantly lower values in comparison to group F during certain period of time. Levobupivacaine was hemodynamically more stable than Bupivacaine. Analgesic drugs were first requested in group F (3.57 ± 0.88h) followed by group B (15.51 ± 1.21h) then group L (17.12 ± 0.98h). Total post-operative opioid consumption in the first 24h was significantly higher in group F (89.14 ± 0.98mg) than in group B (29.59 ± 1.11mg), group L (28.29 ± 0.78mg). However, the Ramsey sedation score showed no statistically significant difference among the three groups.

Conclusion: Regional analgesic techniques have better hemodynamic control and postoperative analgesic effect when compared to intravenous opioid infusion. Moreover, Levobupivacaine is a good alternative for Bupivacaine in Suprazygomatic maxillary nerve block with longer duration of postoperative analgesia.

Keywords: Bupivacaine; Fentanyl; Levobupivacaine; Maxillary Nerve Block; Maxillofacial Surgery; Ultrasound

Introduction

General anesthesia has been used routinely for maxillofacial surgery with nasotracheal intubation to ensure airway patency and decrease risk of aspiration. Being an invasive and painful procedure, pain control is mandatory in this type of operation [1]. Pain control can be achieved by either intravenous medication such as Opioids, which act directly on the Central Nervous System (CNS) opiate receptors, but they have many side effects such as prolonged postoperative sedation, respiratory depression and aspiration especially in closed mouth. Usage of large doses of Non Steroidal Anti-Inflammatory Drugs (NSAIDs) may be an alternative solution for managing severe postoperative pain, but with major side effect such as peptic ulcer and platelet dysfunction. Another promising solution is unilateral or bilateral block of maxillary nerve for analgesic purposes using local anesthetics [2].

Maxillary nerve provides sensory innervations for the hard and soft palate, maxillary air sinus, posterior nasal cavity, upper lip. Based on these anatomic facts, the maxillary nerve block can be done by intra-oral or extra-oral techniques. Although intra oral technique is commonly used, it has many disadvantages in comparison to extra oral technique e.g., trismus and patient discomfort [3].

Extra oral blocking of maxillary nerve can be done through infra or Suprazygomatic route, but the Suprazygomatic route is preferred as the infrazygomatic route may lead to orbital puncture, intracranial injection and maxillary artery puncture [4]. Maxillary block provides optimal postoperative pain management after maxillary osteotomy in adults [5]. The use of ultrasonographic guidance for regional anesthesia has recently been shown to be beneficial mainly by limiting the puncture complications and block failures by visualization of key anatomical landmarks and confirmation of correct local anesthetic spread [6].

Levobupivacaine is the pure S (−) enantiomers of Bupivacaine. It has less adverse neurological and cardiac effects than Bupivacaine so it is a good substitute for Bupivacaine in regional anesthesia [7]. Up to the end of our knowledge, no available studies addressed Levobupivacaine versus Bupivacaine in ultrasound guided Suprazygomatic maxillary nerve block in adult maxillofacial surgery. The aim of this study was to compare the efficacy of Levobupivacaine versus Bupivacaine on the postoperative pain after maxillofacial surgery. We hypothesized that Levobupivacaine is more potent and safer than Bupivacaine in reducing pain after maxillofacial surgery.

Patients & Methods

This prospective randomized controlled study was approved by ethical committee and the Institutional Research Board (R/16.11.60) of Faculty of Medicine, Mansoura University. Also, informed written consent was signed by 105 patients scheduled for elective repair of maxillary bone fractures at Mansoura University Hospital from September 2014 to September 2015.

Inclusion criteria: Age between 20-50 years of either sex, ASA physical status I or II and patients were scheduled for elective repair of maxillary bone fractures.

Exclusion criteria: Patient refusal, infection at site of injection, hypersensitivity to local anesthetic. Deformities of maxillofacial anatomy, bleeding disorder, cardiac, hepatic and renal failure were also excluded.

Methods

All patients enrolled in this study were randomized by a computer-generated table of random numbers and numbered sealed opaque envelopes containing group. Patients were allocated into three groups (35 patients each): maxillary nerve block in Levobupivacaine group (group-L), maxillary nerve block in the Bupivacaine group (group-B) and Fentanyl group (group-F). Preoperatively, general examination and laboratory investigation was documented for each patient. Visual analogue pain scale (VAS) [8] was explained to all patients in the preoperative visit as graded ruler from 0-10 with VAS 0 indicates no pain up to VAS 10, which is the worst pain. Intravenous access was established and the patient was hydrated with ringer acetate 10 ml/kg. Baseline data was recorded [heart rate, blood pressure, and Peripheral Oxygen Saturation (SpO2)].

Intra operatively, basic patient monitoring, including: Electrocardiogram (ECG), Noninvasive Blood Pressure (NIBP), and SpO2. Adequate pre oxygenation was ensured and anesthesia was induced by 2μg/kg fentanyl, 2mg/ kg propofol, and 0.5mg/kg rocuronium to facilitate tracheal intubation. After full muscle relaxation, reinforced armored nasal Endo Tracheal Tube (ETT) was inserted with lubricant; its proper site was confirmed, secured in place and cap no graph was connected. Anesthesia was maintained with isoflurane 1-2 minimum alveolar concentration with an oxygen/air mixture guided by hemodynamic stability. Subsequent doses of rocuronium 0.15mg/kg were given every 45 min to ensure adequate muscle relaxation. Ventilation was maintained by volume controlled ventilation with initial setting [Tidal Volume (VT) 6ml/kg, Respiratory Rate (RR) 10-15/min, I: E 1:2 and Fio2 0.5] to maintain End Tidal Carbon Dioxide (EtCo2) around 35 mmHg. In (group-F), as a traditional method of operative analgesia, the patient received an infusion of 1 μg /kg/h.

Technique of Maxillary Nerve Block

In group (L, B), the block was performed using 12 MHz high frequency linear ultrasound transducer (Siemens acusonx 300). Liberal amount of sterile ultrasound gel was applied to the skin over the infrazygomatic area with an inclination of 45° in the horizontal plane. A 25-Gauge spinal needle was located at an angle formed by the superior edge of the zygomatic arch below and the posterior orbital rim anterior. The needle was inserted perpendicular to the skin and advanced to reach the greater wing of the sphenoid at approximately 20 mm depth. The needle was then reoriented and advanced 35-45 mm deep to the pterygopalatine fosse.

The pterygopalatine fosse [6] is bounded posteriorly by the root of the pterygoid plates and the inferior surface of the greater wing of the sphenoid bone and anteriorly by the posterior surface of the maxillary bone. The needle was advanced using the out-of-plane approach, and the needle tip was easily identified during movements. Five ml of 0.5% Levobupivacaine in group (L) and five ml of 0.5% Bupivacaine in group (B) was injected over the affected side after negative aspiration. The following data [Heart rate, Mean arterial blood pressure, SpO2 and End Tidal Carbon Dioxide (EtCo2)] was recorded immediately after securing ETT and every 15 min throughout the first hour of surgery and every 30 min up to the end of surgery.

After surgery, all patients were extubated after reversal with neostigmine (0.05mg/kg) and atropine (0.02mg/kg) using the standard criteria of reversal (Sustained head lift for five second and sustained handgrip for five seconds along with adequate spontaneous respiration) the patient was moved to Post Anesthesia Care

Unit (PACU). Postoperatively, all patients were received standard postoperative analgesia (IV 30 mg Ketorolac every 12 hours). Additional doses of 0.5mg/kg IV meperidine was given if VAS ≥ 4. The following data were recorded at 1h, 2h, 6h, 12h, 18h and 24h after arrival to the PACU:

a. Heart rate, mean arterial blood pressure, SpO2.

b. Ramsay Sedation Scale [9] before giving post operative analgesics. Six levels of sedation were formulated; three with the patient awake and three with the patient asleep.

1. Patient anxious and agitated or restless or both.
2. Patient cooperative, oriented, and tranquil.
3. Patient responds only to commands. Asleep levels were dependent on the patient's response to a light glabellar tap or loud auditory stimulus: Level.
4. A brisk response.
5. A sluggish response.
6. No response.

c. VAS, first request for analgesia, total post operative analgesic consumption in the first 24h.

d. Presence of complications e.g. maxillary artery puncture.

Sample Size

Was based on previous study of the efficacy of Levobupivacaine and Bupivacaine for caudal block in children [10] we estimated 25% increase in time to first analgesic request. Based on an alpha error of 0.05 and a pow¬er of 80%, we supposed that approximately 35patients in each group would be sufficient.

Statistical Analysis

The collected data were analyzed using the SPSS version 22 (SPSS Inc., Chicago, IL, USA). Data were tested for normality by using the Kolmogorov-Smirnov test. Chi square or Fisher's exact test was used for analysis of categorical data. Continuous normally distributed data were analyzed by using a repeated measures analysis of variance, followed by post-hoc Bonferroni correction. Non-parametric data were analyzed using Kruskal-Wallis and post-hoc Wilcox on rank sum t-tests, as appropriate. Data are given as mean ± SD; median and range and number (percent). The level of statistical significance was considered at 5% (P value < 0.05).

Results

Figure 1 revealed trial flow diagram demonstrating the disposition of all patients screened for the study. One hundred and eighty of total patients planned for maxillofacial surgery were equally randomized to Bupivacaine, Levobupivacaine or Fentanyl. The total of 31 patients (10 in the Bupivacaine group, 8 in Levobupivacaine group and 13 in Fentanyl group) did not receive the allocated treatment secondary to temporary study drug unavailability in the hospital pharmacy. Dropout rates were 15/50 (30%) with Bupivacaine (2 due to adverse effects, 10 for lack of efficacy, and 3 non-compliance), 17/52 (32.7%) with Levobupivacaine (4 due to adverse effects, 7 for lack of efficacy, and 6 non-compliance) and 12/47 (25.57%) with Fentanyl (2 due to adverse effects, 5 for lack of efficacy, and 5 non-compliance).

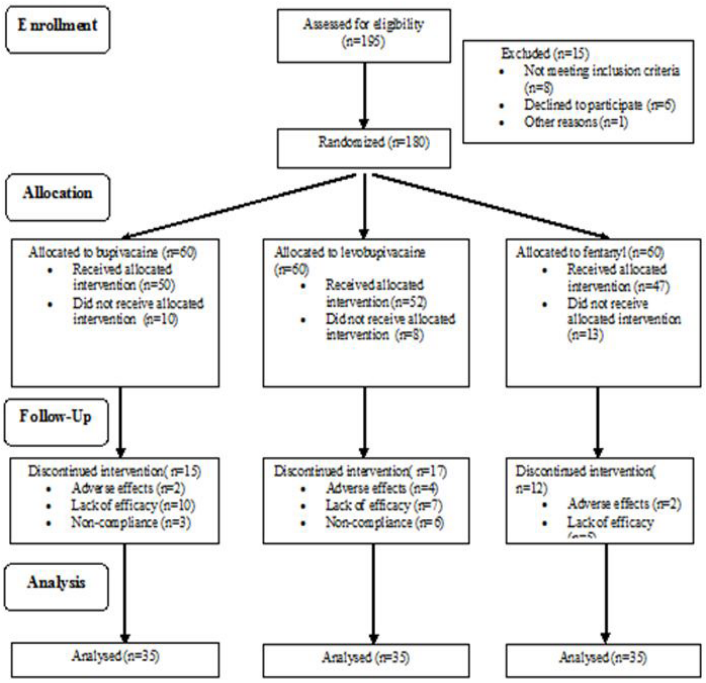

Figure1: Trial flow diagram demonstrating the disposition of all patients screened for the study.

Table 1 outlines patients' demographic characteristics and duration of surgery of the studied group. The study was completed on 105 patients and most of our patients in all groups were females (84.8%) and ASA I (86.7%). Their demographic data (age, weight,

sex, and ASA), and duration of surgery showed no statistically significant difference between the studied groups.

	Group B (n = 35)		Group L (n = 35)		Group F (n = 35)		P value
Age (years)	28.46 ± 10.93		30.40 ± 10.65		31.26 ± 14.27		0.611
Weight (kg)	71.4 ± 14.1		67.9 ± 13.5		68.2 ±13.9		0.505
Duration of surgery (min)	140.9 ± 38.1		124.6 ± 26.0		136.8 ± 30.6		0.09
Sex							
Male	30	85.70%	27	77.10%	32	91.40%	0.246
Female	5	14.30%	8	22.90%	3	8.60%	
ASA							
I	30	85.70%	32	91.40%	29	82.90%	0.562
II	5	14.30%	3	8.60%	6	17.10%	
ASA: American Society of Anesthesiologists, Group B: patients were injected with Bupivacaine, Group L: patients were injected with Levobupivacaine, Group F: patients were injected with IV Fentanyl infusion, *Significant when p value < 0.05.							

Table 1: Demographic characteristics and duration of surgery of the studied groups. Data are expressed as number, %, mean ± SD.

Table 2 shows Heart rate (beats/minute) changes of the studied group. Group B showed significant lower values in comparison to group F at 30min, 60min, 90min, and 120 min intra-operative and at 6h, 12h and 24h postoperative. Also, group B showed significantly higher values at 18h postoperative when compared to group L. Furthermore, group L revealed statistically significant lower values when compared to group F at 90min and 120min intra operative and 6h, 12h, 18h and 24h postoperatively.

Time interval	Group B (n = 35)	Group L (n = 35)	Group F	P value
HR 30 min	80.63 ± 9.39†	82.86 ± 10.52	83.91 ± 10.50	0.045
HR 60 min	77.17 ± 9.79†	80.43 ± 9.70	82.94 ± 10.37	0.04
HR 90 min	76.46 ± 10.92†	79.49 ± 10.21‡	82.66 ± 10.1	0.04
HR 120 min	79.49 ± 10.67†	80.13 ± 9.35‡	83.27 ± 9.85	0.002
HR PO 6H	81.77 ± 9.91†	82.09 ± 7.96‡	86.77 ± 8.86	0.04
HR PO 12H	81.40 ± 8.61†	83.09 ± 7.92‡	87.83 ± 7.85	0.004
HR PO 18H	89.04 ± 9.01*	81.01 ± 8.02‡	90.04 ± 8.02	0.045
HR PO 24H	85.74 ± 9.77†	84.57 ± 8.07‡	88.77 ± 8.56	0.04
Group B: patients were injected with bupivacaine, Group L: patients were injected with levobupivacaine, Group F: patients were injected with IV fentanyl infusion, * Significant when group B compared with Group L,† Significant when group B compared with Group F,‡ Significant when group L compared with Group F,HR: Heart rate, PO: Postoperative, H: hours, min: Minutes. Significant when p value < 0.05.				

Table 2: Heart rate (beat/minute) changes in the studied groups. Data are expressed as mean ± SD (significant data were only displayed).

Table 3 represents Mean Arterial Blood Pressure (MAP) changes of the studied group. MAP was significantly lower in group B when compared to group F at 15min, 30min, 45min, 60min, 90min and 120min intra operative and at 2h, 6h and 12h postoperative. Group L had significant lower values at 30min, 60min during surgery and at 2h, 6h, 12h and 18h after the end of surgery when compared with group F. So Levobupivacaine was hemodynamically more stable than Bupivacaine.

Time interval	Group B (n = 35)	Group L (n = 35)	Group F (n = 35)	P value
MAP 15 min	78.97 ± 8.29†	81.86 ± 8.90	83.23 ± 9.68	0.03
MAP 30 min	77.86 ± 7.95†	81.23 ± 7.69*	85.23 ± 9.35	0.002
MAP 45 min	77.86 ± 8.06†	79.29 ± 14.80	84.29 ± 9.33	0.004
MAP 60 min	76.63 ± 8.13†	78.60 ± 14.94*	83.94 ± 9.33	0.02
MAP 90 min	79.31 ± 6.92†	80.26 ± 8.43	82.51 ± 9.19	0.008

MAP 120 min	77.57 ± 6.40†	79.97 ± 7.01	82.06 ± 8.41	0.001
MAP PO 2H	80.57 ± 5.54†	81.54 ± 6.14*	85.89 ± 6.81	< 0.001
MAP PO 6H	81.86 ± 5.69†	81.94 ± 6.27*	86.60 ± 7.25	0.001
MAP PO 12H	81.43 ± 5.85†	82.00 ± 5.80*	87.11 ± 7.60	< 0.001
MAP PO 18H	85.42 ± 7.81	82.02 ± 6.41*	89.17 ± 7.43	0.02
Group B: patients were injected with Bupivacaine, Group L: patients were injected with Levobupivacaine, Group F: patients were injected with IV Fentanyl infusion, * Significant when group L compared with Group F, † Significant when group B compared with Group F, MAP: Mean arterial pressure, PO: Postoperative, H: hours, min: Minutes. Significant when p value < 0.05				

Table 3: Mean arterial blood pressure changes (mmHg) changes in the studied groups. Data are expressed as mean ± SD (significant data were only displayed).

Table 4 illustrates first request of analgesia, total post-operative opioid consumption in the first 24h and the Ramsey sedation score of the studied groups. Analgesic drugs were first requested in group F (3.57 ± 0.88h) followed by group B (15.51 ± 1.21h) then group L (17.12 ± 0.98h). Total post-operative opioid consumption in the first 24h was significantly higher in group F (89.14 ± 0.98mg) than in group B (29.59 ± 1.11mg), group L (28.29 ± 0.78mg). However, the Ramsey sedation score showed no statistically significant difference among the three groups.

Time interval	Group B (n = 35)	Group L (n = 35)	Group F (n = 35)	P value
First request of analgesia (hours)	15.51 ± 1.21*†	17.12 ± 0.98‡	3.57 ± 0.88	< 0.001
Total post-operative opioid consumption (mg) in the first 24h	29.59 ± 1.11†	28.29 ± 0.78‡	89.14 ± 0.98	< 0.001
Ramsey sedation score 1H	2 (1 - 3)	2 (1 - 3)	2 (1 - 4)	0.3
Group B: patients were injected with Bupivacaine, Group L: patients were injected with Levobupivacaine, Group F: patients were injected with IV Fentanyl infusion, * Significant when group B compared with Group L, † Significant when group B compared with Group F, ‡ Significant when group L compared with Group F, PO: Postoperative, H: hours, min: minutes. Significant when p value < 0.05.				

Table 4: First request of analgesia, total post-operative opioid (meperidine (mg)) consumption in the first 24h and Ramsey sedation score of the studied groups. Data are expressed as mean ± SD.

Table 5 revealed a visual analogue scale of the studied groups. VAS was significantly lower at 1h, 2h, 6h, 12h and 18h after surgery when group B compared to group F. Also, group B showed significantly higher value at 18h postoperative when compared to group L. Moreover, group L showed significantly lower VAS values than group F at 1h, 2h, 6h, 12h and 18h after surgery. No complications were observed in the three studied groups through the overall study.

Time interval	Group B (n = 35)	Group L (n = 35)	Group F (n = 35)	P value
VAS PO 1H	0 (0 - 2) †	0 (0 - 1) ‡	2 (1 - 3)	<0.001
VAS PO 2H	0 (0 - 3) †	0 (0 - 2) ‡	3 (2 - 4)	<0.001
VAS PO 6H	2 (1 - 4) †	2 (1 - 3) ‡	4 (3 - 6)	<0.001
VAS PO 12H	3 (2 – 5) †	3 (2 - 6) ‡	4 (4 - 6)	0.04
VAS PO 18H	4 (4 -5)*†	3 (2 - 5) ‡	5 (4 - 6)	0.04
VAS PO 24H	5 (3 - 6)	5 (4 - 7)	5 (4 - 6)	0.4
Group B: patients were injected with Bupivacaine, Group L: patients were injected with Levobupivacaine, Group F: patients were injected with IV Fentanyl infusion, * Significant when group B compared with Group L, † Significant when group B compared with Group F, ‡ Significant when group L compared with Group F, Significant when p value < 0.05, Visual analogue scale: VAS, PO: Postoperative, H: hours				

Table 5: Visual analogue scale of the studied groups. Data are expressed as median and range.

Discussion

Our study showed lower hemodynamic parameters including heart rate and mean arterial blood pressure in group B and group L when compared to group F. At the same time Levobupivacaine was hemodynamically more stable than Bupivacaine. This was similar to study done by compared spinal anesthesia with isobaric Levobupivacaine with fentanyl and hyperbaric bupivacaine with fentanyl in elective cesarean sections [11]. Regional anesthesia combined with general anesthesia had better control of surgical stress response with optimal hemodynamic control than general anesthesia with Opioids. It is noticed in another study that regional anesthesia has significant reduction of the level of stress hormones as (adrenaline, noradrenaline, cortisol and ACTH) in comparison to Opioids [12]. Kohase et al, 2002 had proved no significant difference in intraoperative hemodynamic parameters between regional and intravenous analgesic groups. With maxillary nerve block, sevoflurane concentration was less compared to the control group [13].

In this study, the first request for analgesia was earlier in group F than group B and group L which was demonstrated by other studies that the duration of action of bupivacaine is 12 hours following peripheral nerve block [14]. The duration of action of ultrasound-guided femoral nerve block with levobupivacaine was 12 hours [15]. While the elimination half-life of fentanyl is 3.1-6.6 hours [16]. Similar to our study, in comparison of general anesthesia versus regional anesthesia in maxillofacial surgery, it was proved that patients with either maxillary nerve block or mandibular nerve had longer time of postoperative analgesia than patients with general anesthesia [1]. Many studies have compared the duration of analgesia of both levobupivacaine and bupivacaine. Some studies proved that the analgesic effect of levobupivacaine is longer than that corresponding to bupivacaine. Casati et al, 2002 compared the analgesic effect of both levobupivacaine and bupivacaine in sciatic nerve block and found that the sensory block was longer for levobupivacaine by about half an hour compared to bupivacaine, which is similar to the result of our study [17]. Others proved that the analgesic effect of bupivacaine is longer than that produced by levobupivacaine. Liisanantti and his colleagues, 2004 compared the analgesic effect of both levobupivacaine and bupivacaine in axillary brachial plexus block and found that the duration of postoperative analgesia was shorter in levobupivacaine than in bupivacaine by one hour, which it is in contrast to our study [18]. Another study denied any difference between both drugs regarding the duration analgesia in interscalene block [16].

In our study, VAS showed lower values in group B and group L than in group F and group B showed significantly higher value at 18 hours postoperative when compared to group L as proved by Rader and his colleagues, 2013 which also have low VAS values in the postoperative period after Suprazygomatic maxillary nerve block with Bupivacaine [3].This study found that VAS and heart rate were significantly higher in group B than group L at 18 hours post operatively. This may be explained by longer analgesic duration of levobupivacaine than bupivacaine as provided by Cox and his colleges, 1998 in their study and revealed that the analgesic effect of levobupivacaine is longer than bupivacaine in supra-clavicular brachial plexus block by two hours [19].

In this study, total post-operative opioid consumption was less in group (B, L) than in group F with no statistical significant difference between group B and L. Similarly showed decreased morphine consumption and post operative nausea & vomiting after bilateral maxillary nerve block in cleft palate repair in children [4]. Sola et al, 2012 also reported that opioid consumption decreased after ultrasound guided Suprazygomatic maxillary nerve block for cleft palate repair in infants [6]. Fortunately, we did not demonstrate any maxillary block related complications. In their study on the post operative analgesic effect of ultrasound guided bilateral Suprazygomatic maxillary nerve block with ropivacaine for postoperative pain control after cleft palate repair was and reported lower pain score without complication related to the maxillary block [6].

Conclusion

Regional analgesic techniques have better hemodynamic control and postoperative analgesic effect when compared to intravenous opioid infusion. Moreover, Levobupivacaine is a good alternative for bupivacaine in Suprazygomatic maxillary nerve block with longer duration of postoperative analgesia.

Recommendation

We recommend that other studies could be done on different types of surgery to evaluate the maxillary nerve block in postoperative analgesia. Also, many studies could be performed by using a different adjuvant to local anesthetics to determine their effect on the maxillary nerve block.

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